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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/982,284	12/01/1997	HENRYK LUBON	030523/0141	9099

7590 09/11/2003

FOLEY & LARDNER  
3000 K Street Suite 500  
Washington, DC 20007-5109

EXAMINER

WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 09/11/2003

UPO

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application N .

08/982,284

Applicant(s)

LUBON ET AL.

Examiner

Michael C. Wilson

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 6-30-03 and 9-8-03 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 30 June 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 75-100.

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☒ Other: See Continuation Sheet

**MICHAEL WILSON**  
**PRIMARY EXAMINER**

Continuation of 3. Applicant's reply has overcome the following rejection(s): Upon being entered, Applicants response will overcome the claim objections. The response will also overcome the written description and enablement regarding using an osteopontin, urinary kallikrein, urinary thrombomodulin, uropontin, or nephrocalcin regulatory region in the claimed methods or products to obtain expression and secretion of proteins in the urine of a non-human transgenic mammal.

Continuation of 10. Other: The request for reconsideration will not be considered because good and sufficient reasons why it was not earlier presented have not been shown. The claims remain rejected for reasons of record under written description and enablement for using a uromodulin, renin, erythropoietin, apolipoprotein E or aquaporin 5' regulatory region to obtain expression and secretion of a protein into the urine of a non-human transgenic mammal. The claims remain rejected for reasons of record under written description and enablement for expressing and secreting an enzyme into the urine of a non-human transgenic mammal. The claims remain rejected for reasons of record under indefiniteness. It is noted that applicants have not provided any evidence that the uromodulin, renin, erythropoietin, apolipoprotein E or aquaporin promoters would cause expression and secretion of a protein into the urine of a non-human transgenic mammal. The existence of such promoters is not adequate to overcome the art established unpredictability in the art of record (Simonet for example) to obtain protein expression in the tissue of interest in transgenic mammals.